UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

DOUG INGRAM, et al., Plaintiffs, v. SOLKATRONIC CHEMICAL, INC. and JEFF R. HANNIS, and AIR PRODUCTS AND CHEMICALS, INC., a Delaware corporation, et al. Defendants.	Case No. O4CV287EA(C)

DEFENDANT SOLKATRONIC CHEMICAL, INC.'S POST-HEARING BRIEF IN SUPPORT OF MOTION *IN LIMINE* TO EXCLUDE PLAINTIFFS' CAUSATION EXPERTS

Defendant Solkatronic Chemical, Inc. ("Solkatronic") asks this Court to exclude Drs. Richard Hastings, Shayne Gad and Robert Harrison from testifying in this case because they fail to meet the standards of FED. R. EVID. 104 and 702.

INTRODUCTION

The plaintiffs cannot show any reliable scientific or medical support for the opinions of their experts.[1] In the *Daubert* hearing, the plaintiffs and their experts argued, without support, that the signs and symptoms of arsine poisoning may be delayed and that the many lab tests in this case are inconclusive because they may have been taken at the wrong times. They argued that there is variability in human responses, though there was little variability in the plaintiffs' responses (*i.e.*, everyone developed ongoing, nonspecific injuries without hemolysis). They argued that it would be "impossible" to reconstruct the event to provide dose information. Most significantly, the plaintiffs'

[1] Pursuant to this Court's request, this brief is limited to ten pages and contains minimal legal citations. Solkatronic would be happy to provide additional briefing if desired.

experts argued that arsine causes permanent injuries by transforming to arsenic within the body without causing hemolysis.

Even if the plaintiffs' experts' theories and arguments were true (and they are not), they ***prove*** nothing. At best, they are excuses for a lack of evidence, but the plaintiffs have the burden of proof both in this case generally and with specific regard to establishing the admissibility of their expert testimony. The plaintiffs and their experts simply have not put forth any *reliable* and *scientific* evidence to support their contention that *somehow* arsine caused the plaintiffs' various, allegedly permanent, non-specific complaints (*e.g.*, headaches, fatigue, memory loss, etc.) without causing any of the well established signs and symptoms of arsine poisoning.

I. The Plaintiffs' Experts' Failure to Estimate Dose in a Scientifically Reliable Manner Is Fatal to Their Opinions.

Reliable, scientific information regarding dose is a necessary element of a proper methodology in a toxic tort case. *See* Solkatronic's Primer at 18-21. "At a minimum, the expert testimony should include a description of the method used to arrive at the level of exposure and scientific data supporting the determination." *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 781 (10th Cir. 1999). "[F]or most substances, if a plaintiff cannot in some way estimate the level of exposure, he will lose on causal grounds." Ex. 27-J at 430.[2]

The plaintiffs' experts did not develop any reliable, scientific estimates of the dose of arsine to which the plaintiffs might have been exposed. They have no data to show that the concentration and duration of arsine at any location exceeded the NOAEL, IDLH or any other standard. Although they noted that the odor threshold is ten times the

[2] For convenience, the exhibits in this brief are cited with the numbers used in Solkatronic's Primer.

OSHA permissible exposure limits, they ignored the fact that the OSHA standard is based on an eight-hour time weighted average which cannot apply to the incident.

The plaintiffs should have prepared an air dispersion model to estimate the direction, concentration and duration of the release. The plaintiffs' experts argued that it was impossible to *reenact* the event (which is true), but they were wrong to suggest that they could not estimate the event through modeling. Indeed, they recognized that modeling would be important and relatively easy to do, Ex. 17, and even had an article describing how to model – coincidentally enough – an arsine release, Ex. 27-U at 454-59.

The plaintiffs' attempt to establish exposure by questioning Dr. Pike about Solkatronic's risk management plan (RMP) cannot substitute for scientific evidence regarding dose. Dr. Pike was not offered as an expert in air dispersion modeling, and the plaintiffs' experts admitted they have no such expertise.[3] Moreover, the scenarios described in the RMP (including the worst-case analysis) involved a release of substantially more arsine under different environmental conditions (temperature and wind) when compared to what actually happened on July 11, 2001. Obviously, one cannot take the radius of the zone of danger predicted in Solkatronic's worst-case scenario and "divide it in half" (as suggested by the plaintiffs). This is not science; it is guess-work.

II. The Plaintiffs' Experts Offered No Scientific Support for the Theory that Arsine Can Cause Injury without Hemolysis.

The literature cited by the plaintiffs and their experts does not support their theory that arsine can cause the injuries alleged by the plaintiffs[4] and certainly does not support the theory that it can do so in the absence of hemolysis.

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[3] Hastings 287, ll. 11-23 (Ex.3); Gad 99, ll. 15-16 (Ex. 2), and Harrison 145, l. 22–146, l. 1 (Ex. 1).

[4] Although the scientific literature establishes that arsine poisoning may cause nonspecific symptoms such as headaches and fatigue, these symptoms occur in connection with the acute, toxic event.

- The plaintiffs rely on a suggestion in a 1992 article by Drs. Carter and Sullivan that GSH synthesis may inhibit hemolysis. Ex. 27-H. Dr. Carter explained in a 2003 article that he subsequently tested and disproved this theory. Ex. 27-F.

- The plaintiffs rely on Dr. Carter's statement in his 1992 article that "at intermediate doses" there may be a "significant latency period" for hemolysis. Dr. Carter testified that he was referring to a latency period measured in minutes - not hours or days. In fact, Dr. Carter published research in 1997 that shows that hemolysis begins within 5-10 minutes and is fully underway within 30 minutes after exposure. Ex. 27-G.

- The plaintiffs' experts also testified that arsine can cause direct end-organ damage without causing hemolysis. Dr. Carter testified that kidney damage without hemolysis has only been established in laboratory experiments in which the kidney cells are artificially isolated from red blood cells and forced to interact with arsine. As to direct heart damage, Dr. Carter reported that he tested this theory on the heart cells of rats and found no evidence of such damage (and certainly not in the absence of hemolysis).

- The plaintiffs rely on the Apostoli article (Ex. 27-C), but that article does not establish that arsine causes direct end-organ damage and certainly not in the absence of hemolysis. As admitted by Dr. Hastings and made clear in a companion article, the patient in the Apostoli study had massive hemolysis.

- The Risk article (Ex. 12 to Plaintiffs' literature submission) is also unavailing. That article involved chronic exposures, and even Dr. Hastings admitted that it does not support his theory in this case.

- The plaintiffs' experts cite to Levy et al, *Asymptomatic Arsine Nephrotoxivity* to support their theories. This article – never mentioned by the plaintiffs' experts until the *Daubert* hearing - highlights the caution that courts recognize in relying on case reports rather than controlled studies. This article does not establish that either of the two persons at issue were, in fact, exposed to arsine, and does establish whether such exposure (if any) was acute or chronic. Indeed, both subjects were exposed to other heavy metals, and there is no explanation of how arsine could have been present in their environment. The patient at issue had no arsenic in his hair samples, suggesting that he may not have been exposed

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No scientific literature supports the claim that an acute arsine exposure causes alleged chronic, recurrent, and/or persistent headaches, fatigue, and shortness of breath four years after the alleged exposure.

> to arsine. Finally, the case report does not, and cannot, rule out other causes of the patient's relatively minor kidney damage.

There is simply no medical or scientific support for the plaintiffs' "groundbreaking" theory that a single acute exposure to arsine can cause permanent nonspecific symptoms without causing any of the established signs and symptoms of arsine poisoning.

III. Dr. Hastings Should Be Excluded Under Fed. R. Evid. 104 & 702.

The only apparent methodology employed by Dr. Hastings in this case was to attribute the complaints of any plaintiff who presented in his office to something released by Solkatronic at some point in time. Dr. Hastings did this for plaintiffs who were upwind and downwind, for plaintiffs who arrived 7, 8, and 9 hours after the event, and even for plaintiffs who were not there at all on July 11, 2001 (*e.g.*, Hinton and Shavers). Dr. Hastings (like Dr. Harrison) reached his differential diagnosis without dose or exposure information and despite the fact that ***none*** of the plaintiffs in this case experienced the classic signs and symptoms of arsine poisoning. Even Drs. Gad and Harrison agreed that there was insufficient information to diagnose arsine injuries in many of the plaintiffs diagnosed by Dr. Hastings.

Dr. Hastings is not a toxicologist. He has no specialized training beyond being certified as an internist. Dr. Hastings' entire knowledge of arsine exposure is limited to a series of articles and journals he obtained after being contacted by Plaintiffs' counsel in this litigation. He never examined a person with possible arsine exposure prior to the incident, and he first saw the lead plaintiffs 1 ½ to 2 years after the incident. He has never published any articles relating to toxicology, arsine, or arsenic. Dr. Hastings has not participated in or published any research projects relating to arsine or any other chemical or gas exposures. He does not belong to any professional toxicological

organizations, such as the Academy of Toxicological Sciences or the Society of Toxicology. He has not received an academic appointment or taught courses that have anything to do with toxicology. Dr. Hastings fails each and every qualification criteria set forth in Ex. 27-AJ at 415 to 418. Dr. Hastings should not be permitted to testify as to the cause of the plaintiffs' injuries when such testimony requires an expertise in toxicology and/or experience in dealing with arsine gas, neither of which he possesses.

Likewise, Dr. Hastings lacks the qualifications to offer the opinion that most of the plaintiffs suffer from either depression or Post Traumatic Stress Disorder ("PTSD") as a result of the accident on July 11, 2001. He is not a degreed or licensed psychiatrist or psychologist. Hastings 453, ll. 5-9 (Ex. 3). Nothing suggests he has the slightest training or experience in evaluating individuals with any type mental disorders or injury other than what he did as an intern or resident in obtaining his osteopathic medicine degree. *Id.* 417, ll.11–25 (Ex. 3). In arriving at the mental health disorder "diagnosis," he failed to follow the Diagnostic and Statistical Manual of Mental Disorders, known as "DSM-IV," published by the American Psychiatric Association - the authority that defines diagnoses made by mental health professionals. *Id.* 416, ll. 4-8 (Ex. 3).

Dr. Hastings' opinions fail all of the *Daubert* criteria. His opinions have not been tested. His theories (that he characterizes as "groundbreaking") have not been peer reviewed. Dr. Hastings' theories are subject to the likelihood of a high error rate, since they have never been published or peer reviewed by the scientific community (and since they attribute a wide range of non-specific symptoms with many causes to a specific event that occurred years ago). Equally lacking is any acceptance of his "theories" of causation. In fact, the universal body of medical literature on arsine gas is ***contrary*** to his position. In short, he developed his opinions for the sole purpose of litigation.

Dr. Hastings is unqualified to offer, and has no reliable, scientific evidence to support, his "groundbreaking" opinions on general and specific causation. *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.")

IV. Dr. Harrison Should be Excluded under FED. R. EVID. 104 & 702.

Dr. Harrison did not follow an acceptable methodology. In fact, Dr. Harrison had to agree that he did not even follow his *own* methodology. *See* Harrison 212, l. 13–217, l. 1 (Ex. 1). For example, although Dr. Harrison testified that it is "always" important to consider the credibility of the plaintiff and the possibility that a plaintiff is exaggerating for secondary gain, he admitted that he has never spoken to any of the plaintiffs in this case and that he is "assuming" their credibility. *Id.* at 228-229, 275.

Dr. Harrison claims he performed a "differential diagnosis" but failed to include many critical pieces of information. During his deposition, he admitted that he was unaware of many relevant preexisting conditions for the lead group of plaintiffs. Harrison 119, l. 23–120, l. 8; 317, l. 1–319, l. 5 & 334, l. 21 – 335, l. 10 (Ex. 1). Dr. Harrison also admitted he has never seen or spoken to any of the plaintiffs and that he has not read the plaintiffs' depositions. Instead, he testified that he relied on the medical records of the plaintiffs and, in part, Dr. Hastings' (unreliable, unscientific) reports. During the hearing, Dr. Harrison admitted that he must not have read the medical records very carefully because he had not noticed, for example, that Hinton's records show that he awoke with his symptoms and left the Port two hours before the accident.

Perhaps most damning, however, for Dr. Harrison's differential diagnosis is the fact that he was unaware of the temperature on July 11, 2001 (Harrison 121, l. 8-10 (Ex. 1)), or how long the plaintiffs were left outdoors before being transported to local

hospitals. *Id.* at 280, l. 18-24 (Ex. 1) ("I don't have that detailed information."). Without this information, Dr. Harrison could not even *consider*, let alone rule out, the most likely alternative cause – dehydration and heat stress – of the plaintiffs' alleged symptoms on July 11, 2001.[5] *See* Exs. 13, 14 & 15 & Harrison 121, l. 18–122, l. 23 (Ex. 1).

Dr. Harrison's "epidemiology" is also unreliable. Using the map prepared by the plaintiffs' counsel showing 19 persons with allegedly elevated plasma free hemoglobin readings, he argued that it is statistically improbable and statistically significant that 5 of the 12 initial plaintiffs and 19 of the 192 total plaintiffs have elevated plasma free hemoglobin readings.[10] According to his past testimony, these are not the right numbers to use for a statistical analysis. The proper denominator for such an analysis is *not* the hand-selected lead trial group or the 192 people who decided to sue Solkatronic.[6] Instead, as Dr. Harrison explained in his deposition, the proper denominator is the population of people at risk on the day of the event and/or the population of people who went to the hospital for treatment.[7]

On top of this, Dr. Harrison ignored other possible reasons for the elevations in these persons' plasma free hemoglobin. For example, lipemia can cause a false high reading as seen in Mr. Sumter's blood sample (labeled as lipemic). In his deposition, Dr. Harrison admitted that he did not know how a plasma free hemoglobin test was done or whether lipemia could effect such a test. Harrison 238, l. 9–239, l. 11 (Ex. 1). Dr. Banner explained that, at St. Francis hospital (where Sumter was seen), Sumter's blood

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5 *See also* Solkatronic's Primer, at 22-26.

6 Dr. Harrison admits he does not have the information on the total denominator or how many were tested. Harrison 191, ll. 15-17 (Ex.1) ("I don't have the information on the total denominator . . . .").

7 Dr. Harrison's numerator is also unreliable. Two of the 19 persons were not present at the time of the release (Hinton and Harper) and one has no records in this case (Aguirre). Five were located away from the prevailing wind (Aguirre, Coatny, Hessman, Linley, and Thrasher). Without a reasonable opportunity for exposure, these persons are not part of the population of persons at risk and there is no scientific basis for concluding that their plasma free hemoglobin readings are relevant in this case. To the contrary, these readings suggest that there are other causes of these readings. *See infra.*

sample would not be "cleared" before the plasma free hemoglobin test was performed. Plus, the process of collecting blood samples in an emergency room can also cause minor hemolysis. The doctors at St. John's (where 11 of the 19 were treated) believed that the elevated readings at their hospital were artifacts due to the blood draws. (Ex. 23).[8]

Dr. Harrison first opined that all 13 of the plaintiffs experienced symptoms consistent with arsine poisoning.[9] At his deposition, he retracted his opinions with regard to Biddle, Guerra, and Shavers. *Id.* at 153, l. 1-155, l. 25 (Ex. 1). At the *Daubert* hearing, he also retracted his opinions regarding Hinton and Schnitzer. The plaintiffs appears to believe that, although Dr. Harrison had to withdraw almost half of his specific causation opinions, he should be allowed to testify as to the remainder because he might have gotten *those* opinions right. This is not how it works. Under *Daubert*, the focus is on the expert's methodology, not his results. Having made so many errors, it is clear that Dr. Harrison has not used a *reliable* and *scientific* methodology, if he used a methodology at all.

V. Dr. Gad Should be Excluded.

Dr. Gad is a toxicologist, but not a medical doctor. Gad, 70, ll. 9-11 (Ex. 2). As such, he is not qualified to give specific causation opinions. *See Conde v. Vesicol Chemical Corp.*, 105 F. Supp.2d 21, 27 (N.D. Ohio 1992), *aff'd* 24 F.3d 809 (6th Cir. 1994); *Goewey v. United States*, 886 F. Supp. 1268, 1281 (D.S.C. 1995); *Heller v. Shaw*

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[8] Dr. Harrison acknowledged that the apparent "cluster" of elevated readings at Air-X-Changes may exist simply because "the individuals of Air Exchangers [could] happen to be the ones to go to the emergency department and happen to be the ones to get plasma hemoglobins drawn." *See* Harrison 192, ll. 5-8 (Ex. 1). In fact, this is exactly what happened. Those persons downwind of the release were encouraged to go to the hospital for evaluation. In contrast, although there are approximately 50 plaintiffs from Erlanger to the northeast of Solkatronic, none of these plaintiffs went to the hospital on July 11, 2001. If they had, there might be a similar, meaningless "cluster" of not-clinically-relevant, slightly elevated plasma free hemoglobin readings to the northeast of Solkatronic.

[9] *See* Harrison's Expert Report, attached as Ex. 1 to this brief.

Indus., Inc., 167 F.3d 146, 153 (1st Cir. 1999). Yet, this is all that was in his initial expert report. Dr. Gad has now withdrawn the specific causation opinions in that report.

Dr. Gad cannot be permitted to testify regarding general causation. Although his rebuttal report arguably included such opinions, these opinions were untimely. Pursuant to Rule 26, the parties were required to present "all" of their experts' opinions in their initial reports. *See* FED. R. CIV. P. 26(a)(2)(B); *Reed v. Binder*, 165 F.R.D. 424, 429 (D.N.J. 1996). Here, the plaintiffs have the burden of proof on general causation, and any opinions on that subject should have been in their experts' initial reports. *See, e.g., Donnelly v. Ford Motor Co.*, 80 F. Supp.2d 45, 50 (E.D.N.Y. 1999).

At the *Daubert* hearing, Dr. Gad testified that he is now offering the opinion that an acute[10] exposure to arsine can cause serious injury without causing hemolysis. This theory is not in any of Dr. Gad's reports, and neither is the literature that he cited at the hearing in support of his new theory. As was discussed *supra* in Section II, no medical or scientific literature supports Dr. Gad's general causation theory that serious injuries can result from arsine exposure without hemolysis. Dr. Gad has offered no independent testing or laboratory research to support his theory, and his opinions are inadmissible under the standards of Rules 104 and 702.

CONCLUSION

For the foregoing reasons, Defendant Solkatronic Chemical, Inc. asks this Court pursuant to FED. R. EVID. 104 & 702 to exclude the plaintiffs' experts, Drs. Richard Hastings, Shayne Gad, and Robert Harrison from testifying in this lawsuit.

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[10] Although Dr. Gad suggested in his rebuttal report that chronic exposure to arsine might have such effects, there is no reliable, scientific evidence in this case of any such exposure. In his deposition, Dr. Gad agreed that he is not opining that any of the plaintiffs were exposed chronically.